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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
1652	24

DATE MAILED: 07/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/808,031	INOUYE ET AL.	
	Examiner	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8,10,12 and 15-17* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8,10,12 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants amendment of claims 1, 2, 4, 7, 10, 12, 15 and 17 and cancellation of claims 3, 9, 11, 13, and 14 without prejudice is acknowledged. Claims 1, 2, 4-8, 10, 12 and 15-17 are still at issue and are present for examination.

Applicants' arguments filed on 4/29/2002, Paper No. 43, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Newly submitted claim 10 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 10 is now drawn to a reverse transcriptase extension in vitro screening method which is related to the currently examined claims 1, 2, 4-8,12 and 15-17 drawn to a reverse transcriptase as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, the reverse transcriptase, can be used in other methods such as methods for synthesizing DNA.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

prosecution on the merits. Accordingly, claim 10 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

The disclosure is objected to because of the following informalities: Previously it was pointed out to applicants that on page 11, lines 17-22, the specification recites "Xiong and Eickbush (1990)", "Hsu et al. 1992b", "Sun et al. 1991" and "Herzer et al. 1992", yet these references are not listed with the other references in the specification so it is unclear as to the exact citation upon which applicants are referring. In response to this objection applicants have amended the specification to include the journal title for "Xiong and Eickbush (1990)", and "Hsu et al. 1992b" but have not commented with respect to the references "Sun et al. 1991" and "Herzer et al. 1992", therefore the objection remains for these references. Further the recitation "Hsu et al. J. Bact., 174 (7): 2384-2387, April 1992b" is confusing with regard to "1992**b**". Does the "**b**" have some significance used in this context?

Appropriate correction is required.

Claim Objections

Claim 7 is objected to because of the following informalities:

Newly amended claim 1, line 4 recites "...and further compris**ing**...". This should be "...and further compris**es**..." to maintain consistency with in the claim (i.e. see earlier

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claim 12 is indefinite in part (4) which merely recites "an amino acid sequence Xaa_7 is a polar residue selected from the group consisting of arginine, lysine, glutamic acid, glutamine and valine.", as a single amino acid "Xaa_7" is not an amino acid sequence.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-6, 12, 15, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was stated in the previous office action as it applied to previous claims 1-6, 9, 10, 11, 12, 13-16 and 17. Applicants have cancelled claims 3, 9, 11, 13 and 14.

Applicants have amended the remaining claims and traverse this rejection on the basis that the amendments to the claims place them in proper form for allowance. Applicants reference to claim 10 in supporting their position is not clear as discussed above, claim 10 has been amended such that it is now drawn to a different invention and has been withdrawn. While applicants submit that the rejected claims recite both structure and function, the claims remain rejected on the basis that the "structure" that is recited is not sufficient such that the skilled artisan would recognize Applicants were in possession of the claimed invention. The mere recitation of a four or five amino acid motif conserved among a number of bacterial reverse transcriptases that hundreds of amino acids in length is not an adequate structural description.

Given this lack of an adequate structure to function/activity relationship of the disclosed RT species, the skilled artisan would not recognize applicants were in possession of the claimed genus.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 8, 10, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lim and Mass (Cell 56:891-904, 1989).

This rejection was stated in the previous office action as it applied to previous claims 1, 2, 5, 6, 8, 9-11, 13-16. Applicants have cancelled claims 9, 11, 13 and 14.

Applicants traverse the rejection on the basis that Lim and Mass fails to teach or suggest the presence of an amino acid sequence comprising Asn-Xaa_1-Xaa_2 and therefore cannot anticipate amended claims 1, 2, 5, 6, 8, 10, and 15-16. While Lim and Mass do not teach or suggest the presence of the sequence Asn-Xaa_1-Xaa_2, this amino acid sequence is an inherent property of the bacterial reverse transcriptase taught by Lim and Mass, and therefore Lim and Mass anticipate the rejected claims even without specifically disclosing this sequence.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-8 and 15-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over either of Inouye et al. (US Pat. 5,320,958 or US Pat. 5,434,070), in view of the combination of Rice et al. (July 1993), Xiong et al. (1990) and Hsu et al. (Apr. 1992).

This rejection was stated in the previous office action as it applied to previous claims 1-11, 13-17. Applicants have cancelled claims 3, 9, 11, 13 and 14.

The rejection is stated in the previous office actions, paper Nos: 24, 36 and 38, and applicants present arguments in paper Nos: 26 and 37.

Applicants traverse this rejection on the basis of applicant's submission of a Declaration under 37 C.F.R. 1.131 swearing behind the publication by Rice et al. (July 1993). It is noted that applicants declaration is not signed by all of the inventors, and is missing the signature of Inventor Jorge Vallejo-Ramirez, whom applicants have submitted was unavailable for signature. Applicants have submitted a petition under 37 C.F.R. 1.47 supporting applicants diligence in obtaining the signature of Mr. Vallejo-Ramirez. Regardless of whether such a petition is necessary, such a petition must be looked at by the office of petitions. Regardless of the decision of the whetner applicants attempt to obtain the signatures of all the inventors was sufficient, the 1.131 declaration is not sufficient as there is no showing of facts to support the allegation of prior reduction to practice (See M.P.E.P 715.07). Therefore the rejection of claims 1, 2, 4-8 and 15-17 is maintained.

Claims 1, 2, 4-6, 8, 10, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu et al. (Journal of Bacteriology 174(7): 2384-2387, April 1992), as

applied to claims 1, 2, 4-8 and 15-17 above, and further in view of Lim and Mass (Cell 56:891-904, 1989).

This rejection was stated in the previous office action as it applied to previous claims 1-6, 8, 9-11, 13-17. Applicants have cancelled claims 3, 9, 11, 13 and 14.

Applicants traverse this rejection on the basis that the teaching of Hsu et al. that only 13% of E. coli natural isolates contain retrons and those retrons show substantitial diversity teaches away from the motivation to combine the references as previously stated. This argument is not found persuasive because the showing of differences between species does not teach away from the combination of two references that each teach about the occurrence of reverse transcriptases in different bacterial species. This is supported in the introduction of Hsu et al. where they discuss the homologies of msDNA from *M. xanthus* and *E. coli* and reference the Lim and Mass paper.

One of ordinary skill in the art would have been motivated to express the nucleic acid sequence taught by Hsu et al. to confirm Hsu et al.'s hypothesis that the nucleic acid encodes a protein with reverse transcriptase activity. The reasonable expectation of success comes from the high degree of knowledge in the art with respect to the expression of recombinant proteins as is demonstrated by Lim and Mass (Cell 56:891-904, 1989).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Richard Hutson, Ph.D.
Patent Examiner
Art Unit 1652
July 3, 2002

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600